



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2014-0680; FRL-9940-90]

### Propyzamide; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of propyzamide, also known as pronamide, in or on leaf lettuce. Dow AgroSciences, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0680, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202)566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify the request by the docket ID number EPA-HQ-OPP-2014-0680 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0680, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of Wednesday, December 17, 2014 (79 FR 75109) (FRL-9918-90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8301) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268-1054. The petition requested that 40 CFR 180.317 be amended by establishing a tolerance for residues of the herbicide pronamide (propyzamide) and its metabolite containing the 3,5-

dichlorobenzoyl moiety calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide, in or on lettuce, leaf at 1.0 part per million (ppm). That document referenced a summary of the petition prepared by Dow AgroSciences, LLC, the registrant, which is available in the docket EPA-HQ-OPP-2014-0680 at <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe”. Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information”. This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for propyzamide including

exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with propyzamide follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Propyzamide has low acute toxicity via the oral, dermal, and inhalation routes of exposure, is non-irritating to the eyes or skin, and is not a dermal sensitizer.

The primary target organ for propyzamide is the liver. There are other target organs as well, including the thyroid, testes, and pituitary, but effects on these organs are secondary to primary effects on the liver. Liver-related effects include increases in absolute and relative liver weights, hypertrophy, elevated levels of enzymes associated with liver damage, and histopathology of liver cells. Adverse liver effects were consistently observed in every animal species studied, with progression towards more severe effects over time ultimately leading to tumorigenesis in rats and mice. Based on the studies submitted, the rat is the most sensitive species. In most studies, there is no gender sensitivity in response to propyzamide.

Propyzamide is a carcinogen in rats and mice, causing liver tumors in mice, thyroid tumors in male rats, and testicular tumors in rats. Based on MOA studies, tumorigenesis for all three tumor types has been shown to be mediated by liver enzymes

induced in response to treatment with propyzamide. In mice, the MOA data clearly show rapid induction of *Cyp2b10* associated with the constitutive androstane nuclear receptor (CAR), as well as induction of peroxisomes and peroxisomal enzymes such as *Cyp4a10* associated with a second nuclear receptor, PPAR- $\alpha$ . Induction of the nuclear receptors leads to mitogenesis followed by hepatocellular proliferation and eventually, liver tumors.

In rats, propyzamide induces *Cyp2b1* 200-fold over background levels, but has no effect on other CYPs commonly associated with carcinogenic modes of action. In the rat *Cyp2b1* is a biological marker for the CAR receptor. The CAR pathway is associated with the activation of uridine diphosphate glucuronyl transferase (UGT) which catalyzes the condensation of glucuronic acid with thyroxine (T4), leading to enhanced biliary excretion of T4. Eventually the continued stimulus to produce more T4 leads to the formation of thyroid follicular tumors. In male rats, the tumorigenic dose of propyzamide for both thyroid tumors and Leydig cell tumors is 1,000 ppm in the diet (34-75 mg/kg/day based on age of the rats). Tumor precursor effects such as decreases in T4 levels, increases in liver weight, liver hypertrophy, and elevated testosterone metabolism occur at doses below or equivalent to the tumorigenic dose.

In nearly every oral repeated-dose study of propyzamide as well as in the 28-day dermal toxicity study in rats, there were dose-related decreases in body weight, body weight gain, and food consumption. Typically, these effects on body weight occurred at or above effects on the liver such as hypertrophy or increases in liver weight.

There was evidence of neurotoxicity in rats based on an increase in landing foot splay in females and decreases in motor activity in both genders in the acute neurotoxicity study. In the subchronic neurotoxicity study however, there was no evidence of neurotoxicity following dietary administration, and only body-weight effects were observed. There was no evidence of neurotoxicity in the rest of the toxicology database across other species or other strains of rat. There was no evidence of immunotoxicity.

There was no evidence of quantitative or qualitative increased susceptibility in the fetuses or the offspring of rats or rabbits following pre- and/or postnatal exposure to propyzamide. In the prenatal developmental toxicity study in rabbits and the multi-generation reproduction study in rats, any observed toxicity to the fetuses or offspring occurred at equivalent or higher doses than effects to parental animals.

Specific information on the studies received and the nature of the adverse effects caused by propyzamide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “*Pronamide Human Health Risk Assessment for Registration Review and to Support New Section 3 Use on Leaf Lettuce (Revised)*” on pages 14-22 in docket ID number EPA-HQ-OPP-2014-0680.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which



there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for propyzamide used for human risk assessment is shown in Table 1 of this unit.

**Table 1.--Summary of Toxicological Doses and Endpoints for Propyzamide for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
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Acute dietary (All populations)	LOAEL = 40 mg/kg/day  UF <sub>A</sub> = 10x  UF <sub>H</sub> = 10x  UF <sub>L</sub> = 10x  FQPA SF = 1x	Acute RfD = 0.04 mg/kg/day   aPAD = 0.04 mg/kg/day	<u>Acute Neurotoxicity Rat Study</u>  No NOAEL established  LOAEL = 40 mg/kg/day based on increased landing foot splay and decreased motor activity
Acute dietary (Females 13-49 years of age)	No endpoint attributable to a single exposure was identified, including developmental toxicity studies in rats and rabbits.		
Chronic dietary (All populations)	LOAEL = 40 mg/kg/day  UF <sub>A</sub> = 10x  UF <sub>H</sub> = 10x  UF <sub>L</sub> = 10x  FQPA SF = 1x	Chronic RfD = 0.04 mg/kg/day   cPAD = 0.04 mg/kg/day	POD = 4 mg/kg/day based on a weight-of-evidence approach from the following rat studies:  <u>Acute Neurotoxicity Study</u>  No NOAEL established  LOAEL = 40 mg/kg/day based on increased landing foot splay and decreased motor activity  POD = 4 mg/kg/day (LOAEL of 40 mg/kg/day ÷ 10x UF <sub>L</sub> )  <u>Subchronic Neurotoxicity Study</u>  NOAEL = 2.38 mg/kg/day LOAEL = 11.28 mg/kg/day based on significant decreases in body weight, body weight gain, and food

			<p>consumption in males</p> <p><u>Combined Chronic Toxicity/Carcinogenicity Study</u></p> <p>NOAEL = 8.46/10.69 mg/kg/day</p> <p>LOAEL = 42.59/55.09 mg/kg/day based on increased relative liver weight and histopathological lesions in the liver, thyroid, and ovaries</p> <p><u>Male Pubertal Study</u></p> <p>NOAEL = 2.5 mg/kg/day</p> <p>LOAEL = 10 mg/kg/day based on decreased serum T4</p>
Incidental oral short-term (1 to 30 days)	<p>LOAEL = 40 mg/kg/day</p> <p>UF<sub>A</sub> = 10x</p> <p>UF<sub>H</sub> = 10x</p> <p>UF<sub>L</sub> = 10x</p> <p>FQPA SF = 1x</p>	LOC for MOE = 1,000	Same as Chronic dietary section above
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	<p>NOAEL = 100 mg/kg/day (dermal absorption rate = 24%)</p> <p>UF<sub>A</sub> = 10x</p>	LOC for MOE = 100	<p><u>Subchronic Dermal Toxicity Rat Study</u></p> <p>LOAEL = 500 mg/kg/day based on decreases in body weight and food consumption</p>

	UF <sub>H</sub> = 10x  FQPA SF = 1x		
Cancer (oral, dermal, inhalation)	Classification: <b>“Not Likely to be Carcinogenic to Humans”</b> at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propyzamide, EPA considered exposure under the petitioned-for tolerance as well as all existing propyzamide tolerances in 40 CFR 180.317. EPA assessed dietary exposures from propyzamide in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for propyzamide. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that propyzamide

residues were present at tolerance levels in all commodities for which tolerances have been established or proposed, and that 100% of the crops were treated with propyzamide.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that propyzamide residues were present at tolerance levels in all commodities for which tolerances have been established or proposed, and that 100% of the crops were treated with propyzamide.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that propyzamide does not pose a cancer risk to humans at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes. The MOAs were adequately supported by studies that clearly identified the sequence of key events, dose-response concordance and temporal relationship to the particular tumor type. Quantification of carcinogenic risk is not required. The chronic RfD would be protective of both carcinogenic and non-carcinogenic effects observed in the mouse and rat carcinogenicity studies and MOA studies conducted at higher doses. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for propyzamide. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used Tier II screening level water exposure models in the dietary exposure analysis and risk assessment for propyzamide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of propyzamide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Tier II Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM-GW), the estimated drinking water concentrations (EDWCs) of propyzamide for acute exposures are estimated to be 102 parts per billion (ppb) for surface water and 21 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 47 ppb for surface water and 18.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 102 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 47 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Propyzamide is currently registered for the following uses that could result in residential

exposures: turf grass and golf courses. EPA assessed residential exposure using the following assumptions: Post-application dermal and incidental oral exposures for children 1 to < 2 years old (physical activities on turf and hand-to-mouth ingestion of treated soil); and post-application dermal exposure for children 6 to < 11 years old (golfing), children 11 to < 16 years old (golfing and mowing), and adults (golfing, mowing, and physical activities on turf). Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

*4. Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found propyzamide to share a common mechanism of toxicity with any other substances, and propyzamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propyzamide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of quantitative or qualitative increased susceptibility in developing fetuses or in offspring of rats or rabbits following prenatal and/or postnatal exposure to propyzamide.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF was reduced to 1X. This decision is based on the following findings:

- i. The toxicity database for propyzamide is complete.
- ii. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity despite evidence of neurotoxicity in the acute study based on the increase in landing foot splay in female rats and the decrease in motor activity seen in both genders on day 1. This decision is based on no evidence of neurotoxicity in the subchronic study at dose levels tested via different routes of administration, and no



evidence of neurotoxicity in the rest of the toxicology database across other species and other strains of rat.

iii. There is no evidence that propyzamide results in increased susceptibility in *in utero* rabbits in the prenatal developmental toxicity study or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propyzamide in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by propyzamide.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to propyzamide will occupy

46% of the aPAD for all infants < 1 year old, the population subgroup receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic dietary exposure to propyzamide from food and water will utilize 11% of the cPAD for children 1 to 2 years old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3. regarding residential use patterns, chronic residential exposure to residues of propyzamide is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be background exposure level). Propyzamide is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposure results in an aggregate MOE of 1,700 for children 1 to < 2 years old (chronic dietary exposure with post-application incidental oral exposure from turf use). Because EPA's level of concern for propyzamide is a MOE of 1,000 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be background exposure level). Propyzamide is currently registered for

uses that could result in intermediate-term residential exposure. However, since the maximum single and yearly application rates are the same, the short-term assessment is protective of intermediate-term incidental oral exposure.

*5. Aggregate cancer risk for U.S. population.* As discussed in Unit III.C.iii., Propyzamide is classified as “Not Likely to be Carcinogenic to Humans” at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes. Therefore, quantification of aggregate cancer risk is not required.

*6. Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to propyzamide residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodologies are available to enforce the tolerance expression of residues in/on plant commodities (PAM II Method I, using gas-liquid chromatography with electron-capture detection (GLC/ECD)) and livestock commodities (Method GRM 02.21, using gas chromatography with negative-ion chemical ionization mass spectrometry detection (GC/MS)). These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established any MRLs for propyzamide.

## **V. Conclusion**

Therefore, tolerances are established for residues of propyzamide (pronamide), 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide, in or on lettuce, leaf at 1.0 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled

“Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 31, 2015.

Susan Lewis,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.317, add alphabetically “Lettuce, leaf” to the table in paragraph (a) to read as follows:

**§ 180.317 Propyzamide; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * *	* * *
Lettuce, leaf	1.0
* * * *	* * *

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